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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/528,031	03/17/2000	Andrew Shyjan	MNI-056CPCN	3941

959 7590 07/12/2004  
LAHIVE & COCKFIELD, LLP.  
28 STATE STREET  
BOSTON, MA 02109

EXAMINER
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HUFF, SHEELA JITENDRA

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 07/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/528,031	<b>Applicant(s)</b> SHYJAN, ANDREW	
	<b>Examiner</b> Sheela J Huff	<b>Art Unit</b> 1642	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 June 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 106-108,115,117,118,120-133 and 135-143 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 106-108,115,117,118,120-133 and 135-143 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The amendment filed 6/17/04 has been entered.

Claims 106-108, 115, 117-118, 120-133 and 135-143 are pending.

The objection to the specification is withdrawn in view of applicant's amendment.

The objection to claims 126 is withdrawn in view of applicant's amendment.

All rejections under 35 U.S.C. 112, second paragraph, are withdrawn in view of applicant's amendments/arguments.

The rejection of claim 115 under 35 U.S.C. 112, first paragraph, is withdrawn in view of applicant's arguments.

All art rejections are withdrawn in view of applicant's amendment.

### ***Information Disclosure Statement***

The Information Disclosure Statement filed 5/22/02 is acknowledged. A signed copy is attached hereto.

### ***Claim Rejections - 35 USC 112***

Claims 107-108, 115, 117-118, 120-124, 129, 131-133 and 136 are/remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection, rather than

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an enablement rejection under 35 U.S.C. 112, first paragraph. The reasons for this rejection are of record in paper no. 12, mailed 1/2/02.

Applicant argues that the claims are methods claims and are not directed to a genus. The claims are directed to a method of using a genus of polypeptides.

Applicant argues that the MRP-beta variants or homologues are described in the specification and that methods for testing for biological activity are disclosed in the specification. The claims are not solely limited to the polypeptides that have the MRP-beta activity. If applicant were to insert the functional activity into the claim, then this rejection would be withdrawn.

Claims 106-108 and 115, 117-118, 120-133 and 135-143 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for identifying drugs which inhibit MRP- $\beta$  by testing for MRP- $\beta$  expression, for cell survival, or for sequestration of a cytotoxin, does not reasonably provide enablement for identifying stimulatory modulators of MRP- $\beta$ , does not reasonably provide enablement for the scope of the modulators of claim 132, and does not reasonably provide enablement for identifying modulators by testing for sequestration of substrates other than cytotoxins. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The reasons for this rejection are of record in paper no. 12, mailed 1/2/02.

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Applicant argues that testing for stimulatory molecules or sequestration of substrates would be the same as testing for inhibitory molecules and that the amount of experimentation to test the scope of the compounds is not undue. The prior art only discloses the identification of inhibitory molecules, Thereby, giving one skilled in the art guidance as to what types of molecules (referring to types of structure) are needed for proper inhibition. Since neither the prior art nor applicant's specification discloses any inhibitory or sequestration molecules, one skilled in the art would be faced the analysis of the millions and millions of different compounds known to man. This is clearly undue. With respect to the scope of modulators, applicant is still claiming broadly because the claims are directed to the screening of millions and millions of different compounds and applicant has not demonstrated a the screening of a representative number of compounds from the broad genus. The state of the art only screens a few compounds and these compounds certainly do not read on "natural metabolite", "synthetic chemical", etc. Screening this multitude of compounds for inhibitory, stimulatory or sequestration ability would clearly be undue.

### ***New Grounds of Rejection***

#### ***Specification***

The amendment filed 5/13/02 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material

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which is not supported by the original disclosure is as follows: The newly added terminology "as determined by the ALIGN algorithm.... Gap penalty = 4)" at page 35 is new matter..

Applicant is required to cancel the new matter in the reply to this Office Action.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. The hyperlink is found on page 30 of the specification. See MPEP § 608.01.

### ***Claim Rejections - 35 USC § 112***

Claims 107-108, 115, 117-118, 120-124, 129-133 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A NEW MATTER REJECTION.

The newly added terminology "as determined by the ALIGN algorithm.... Gap penalty = 4)" in claims 107 and 108 is new matter. This limitation was not supported by the specification as originally filed.

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Claims 108 and 126 and 132 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. In claim 108, at the end of the claim the "\ " is unclear.
- b. in claim 126, last line "is" should be --in--.
- c. In claim 132, there should be a period after lysate not a comma.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J Huff whose telephone number is 571-272-

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0834. The examiner can normally be reached on Tuesday 5:30am-11:30am and Fridays 6:00am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Sheela J Huff  
Primary Examiner  
Art Unit 1642

sjh